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10/057,178	01/24/2002	Kit S. Lam	8141/9886	5311

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EXAMINER

EPPERSON, JON D

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/057,178

Applicant(s)

LAM, ET AL.

Examiner

Jon D. Epperson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 10, 11, 13, 14 and 16-20 is/are pending in the application.
- 4a) Of the above claim(s) 16-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10, 11, 13 and 14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Status of the Application***

1. Receipt is acknowledged of a Response to a non-final office action, which was dated on February 27, 2006.

2. Please note that the following action is made non-final in view of the newly cited art that was not entirely necessitated by Applicants' amendments. Any previous indication of allowability is also hereby withdrawn in view of the newly cited art.

***Status of the Claims***

3. Claims 1-20 were pending. Applicants canceled claim 1-9, 12 and 15. In addition, Applicants amended claims 10, 11, 13 and 14. Therefore, claims 10, 11, 13, 14 and 16-20 are currently pending.

4. Claims 16-20 are drawn to non-elected species and/or inventions and thus these claims remain withdrawn from further consideration by the examiner, 37 CFR 1.142(b), there being no allowable generic claim.

5. Therefore, claims 10, 11, 13 and 14 are examined on the merits in this action.

***Status of the Claims***

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**Withdrawn Objections/Rejections**

6. All rejections or objections are withdrawn in view of Applicants' arguments and/or amendments. Specifically, Applicants' amendment to claim 14 overcomes the 112, second paragraph rejection. Applicants' incorporation of claim 10 into claim 1 and claim 13 into claim 12 overcomes all of the outstanding prior art rejections (i.e., claims 10 and 13 were not previously rejected over Buettner under 35 U.S.C. § 102 or 103). In addition, the objection to claim 15 is rendered moot in view of Applicants' cancellation of claim 15.

**New Rejection*****Claim Rejections - 35 USC § 103***

~~Withdrawn Objections/Rejections~~  
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.  
12 overcomes all of the outstanding prior art rejections (i.e., claims 10 and 13 were not

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in

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8. Claims 10, 11, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hammond (WO 01/40265 A2) (Date of Patent is **June 7, 2001**) (Filing Date is **December 2, 1999**) (5/29/03 IDS) in view of Tizard et al. (Tizard et al. "DiffScreen: the merging of image subtraction and molecular genetics for the rapid analysis of differentially screened cDNA libraries" *CABIOS* 1994, 10(2), 209-210) (12/13/02 IDS).

For *claims 10 and 13*, Hammond (see entire document) discloses methods of identifying a ligand for a target molecule (e.g., see abstract), which anticipates the claimed invention. For example, Hammond discloses labeling a first mixture of molecules and a target mixture of molecules introducing said first mixture of molecules to a combinatorial library of solid phase supports incubating said combinatorial library with said first mixture of molecules performing a first marking step to mark those of said solid phases supports that have molecules of said first mixture bound to them introducing said target mixture of molecules to said combinatorial library and performing a second subtraction and molecular genetics for the rapid analysis of differentially screened cDNA marking step to mark those of said solid phase supports that have a molecule of said target mixture bound to them (e.g., see paragraph bridging pages 5 and 6, steps (a)-(f), "The method includes (a) incubating a plurality of immobilized ligands [i.e., a combinatorial library of solid phase supports] with a first solution substantially free of the target [i.e., a first mixture of molecules] and that includes one or more agents under conditions which allow for formation of stable complexes between the ligands and agents; (b) contacting the ligand-agent complexes with a probe [i.e., a label] molecule having an affinity for the target; (c) identifying probe molecules bound to the ligand-agent complexes by identifying a transient signal associated with the complexes; (d)

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incubating the ligands with a second solution [i.e., target mixture] that includes the target and the first solution under conditions allowing for formation of stable complexes between the target and ligands and for formation of stable complexes between the agents and the ligands ... (f) identifying probe molecules bound to ligand-target complexes and probe molecules bound to the ligand agent complexes in the second solution by detecting the transient signal”; see also pages 9-11).

For *claim 13*, Hammond further discloses isolating one of said phase supports and determining the chemical structure of a ligand on one of said isolated solid phase supports (e.g., see Example 2, “Sixteen sequences that bind to all three viruses are obtained and their amino acid sequence is determined”; see also page 8, lines 21 and 22, “In some aspects the method includes identifying the sequences of the peptides”).

The prior art teachings of Hammond differ from the claimed invention as follows:

For *claim 10*, Hammond fails to disclose obtain first and second image to mark the solid phase supports wherein said first and second image are graphical images. In addition, Hammond fails to disclose creating a third image identifying those of said solid phase supports that have a molecule of said target mixture bound to them, wherein said third image is created by comparing said first image and said second image and said third image is created by comparing the two images on a pixel-by-pixel basis. Hammond only discloses comparing the two marked libraries, but does not prefer to a graphical image (e.g., see Hammond, page 6, step (g), “comparing the transient signal associated with ligand-probe complexes in the second solution with the transient signal associated with ligand-probe complexes in the first solution”). In addition, Hammond fails to disclose

the creation of a third image based on the first two. Hammond is silent with respect to how the first and second transient signals are compared.

For *claims 11 and 14*, Hammond fails to apply the  $(B-A)/A$  formula on a pixel-by-pixel basis.

However, Tizard et al. teach the following limitations that are deficient in Hammond:

For *claim 10*, Tizard et al. (see entire document) teach the use of imaging techniques that employs obtaining a first and second image and then subtracting said images on a pixel-by-pixel basis to create a third image (e.g., see Tizard et al., figure 1, see especially image (c), which represents the “third” image that is produced by subtracting said first and second images).

For *claims 11 and 14*, Tizard et al. disclose a  $B-A$  on a pixel-by-pixel basis and also further adjusting the formula for overexposure which would read on the  $/A$  step (e.g., see Tizard et al., page 209, column 2, paragraph). “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The Office does not have the facilities to make such a comparison and the burden is on the applicants to establish the difference. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ2d 1922 1923 (PTO Bd. Pat. App. & Int.).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was use the DiffScreen imaging techniques as taught by Tizard et al. to

monitor the two sets of target/ligand libraries as disclosed by Hammond because Tizard et al. explicitly state that the imaging system can be used to monitor two sets of DNA libraries (e.g., see Tizard et al., page 209, see also figure 1), which falls within the “nucleic acid” screening embodiment disclosed by Hammond (e.g., see Hammond, page 6, last full paragraph, “In some embodiments ... the ligand molecules can be ... nucleic acids”). Furthermore, a person of skill in the art would have been motivated to use the DiffScreen imaging technique because it greatly reduces the time spent comparing two sets of libraries by avoiding tedious visual analysis and comparison (e.g., see Tizard et al., page 210; see also figure 1, especially figure 1(c) “subtracted image”), which is exactly the problem faced by Hammond (e.g., see Hammond, page 6, paragraph 1, step (g); see also page 11, first full paragraph, “Subtraction of the first set of signals from the second reveals a set of signals that corresponds to beads that contain ligands that bind specifically to the target”). Finally, a person of ordinary skill in the art would reasonably have expected to be successful because both references disclose the use of autoradiography to image their library members (e.g., compare Tizard, figure 1 to Hammond, page 10, last full paragraph) and the technique does not depend on the nature of the library (e.g., plaques, colonies, solid-phase beads) but, rather, the nature and positioning of the labels (e.g., radioisotopes, fluorophores, etc.).

### ***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the



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organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon D. Epperson, Ph.D.

June 1, 2006

JON EPPERSON, PH.D.  
PATENT EXAMINER



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